DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

AUG 30 2004

Date:

From: Division of Dietary Supplement Programs, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification: VI-28

Firm: Outsource Product Manufacture LLC

Date Received by FDA: 5/27/04

90-Day Date: 8/25/04

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Tanya L. Jackson IDS

95-0316

RPT243

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

AUG 10 2004

Mr. Robert DeWitty, Esq.
Outsource Product Manufacture LLC
111 S. Calvert Street, Suite 2700
Baltimore, Maryland 21202

Dear Mr. DeWitty:

This is to inform you that the notification dated, May 27, 2004, that you submitted pursuant to 21 U.S.C. 350b(a)(2) (section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on May 27, 2004. Your notification concerns the substance called "VI-28" which consists of *Panax ginseng*, "*Cornu cervi pantotrichum*", *Cuscuta chinesis*, *Cnidium monnieri*, and *Kaempferia galanga* that you intend to market as a new dietary ingredient.

According to the notification, you intend to sell 300 milligram (mg) capsules containing 75 mg of *Panax ginseng*, 75 mg "*Cornu cervi pantotrichum*", 60 mg *Cnidium monnieri*, 60 mg *Cuscuta chinesis*, and 30 mg of *Kaempferia galanga*. Under the conditions of use stated in the labeling of your product, the manufacturer recommends that the dietary supplement "VI-28" be used in the following manner: 2 capsules daily for the first month, 2 capsules every two days for the second and third months, and 2 capsules twice a week for the fourth and following months.

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

FDA has carefully considered the information in your submission, and the agency has concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing "VI-28" will reasonably be expected to be safe.

It is unclear on what basis you assert that "*Cornu cervi pantotrichum*" (Pilose antler) that is the subject of your notification is a "dietary ingredient" within the meaning of 21 U.S.C. 321(ff)(1) that may be lawfully used in dietary supplements. As defined in 21 U.S.C. 321(ff), a dietary supplement means, among other things, a "product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

(A) a vitamin;
(B) a mineral;
(C) an herb or other botanical;
(D) an amino acid;
(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)."

Your notification failed to adequately identify the substance called "*Cornu cervi pantotrichum*". There is no information in the notification describing the source of the "*Cornu cervi pantotrichum*" that you intend to market as a dietary supplement. The notification did not describe the manufacturing process used to produce the "*Cornu cervi pantotrichium*" that is the subject of your notification. A description of the method of manufacturing may have helped FDA identify your product. "*Cornu cervi pantotrichum*" is a galenical name and not a Latin binomial which includes the genus and species. FDA has conducted a search and we have concluded that there is no scientific species named "*pantotrichum*". Therefore, it is impossible for FDA to identify the substance contained in the "VI-28" capsules which you intend to market.

In addition, it is unclear to FDA whether the test substances used in the referenced studies are the same as your proposed dietary supplement in your notification, VI-28. Therefore, it is not evident that the test substances used in the referenced studies are qualitatively or quantitatively similar to "VI-28", or how these studies are relevant to evaluating the safe use of your new dietary ingredient under the recommended conditions of use.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that your product containing "VI-28," when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of May 27, 2004. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what

information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter, please contact Linda S. Pellicore, Ph.D., at (301) 436-2375.

Sincerely yours,

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition